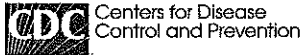


## **EXHIBIT H**



# Selected Adverse Events Reported after COVID-19 Vaccination

Updated Oct. 6, 2021

Print

## Safety of COVID-19 Vaccines

Some people have no side effects. Many people have reported side effects that may affect their ability to do daily activities, but they should go away within a few days.


## What You Need to Know

- COVID-19 vaccines are **safe and effective**.
- Millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring in U.S. history.
- CDC recommends everyone 12 years and older get vaccinated as soon as possible to help protect against COVID-19 and the related, potentially severe complications that can occur.
- CDC, the U.S. Food and Drug Administration (FDA), and other federal agencies are monitoring the safety of COVID-19 vaccines.
- Adverse events described on this page have been reported to the Vaccine Adverse Event Reporting System (VAERS) [↗](#).
- VAERS accepts reports of any adverse event following any vaccination.
- Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem.

Serious adverse events after COVID-19 vaccination are rare but may occur.

For public awareness and in the interest of transparency, CDC is providing timely updates on the following serious adverse events of interest:

- **Anaphylaxis after COVID-19 vaccination is rare** and has occurred in approximately 2 to 5 people per million vaccinated in the United States. Severe allergic reactions, including anaphylaxis, can occur after any vaccination. If this occurs, vaccination providers can effectively and immediately treat the reaction. Learn more about COVID-19 vaccines and allergic reactions, including anaphylaxis.
- **Thrombosis with thrombocytopenia syndrome (TTS) after Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccination is rare.** As of September 29, 2021, more than 14.9 million doses of the J&J/Janssen COVID-19 Vaccine have been given in the United States. CDC and FDA identified 47 confirmed reports of people who got the J&J/Janssen COVID-19 Vaccine and later developed TTS. Women younger than 50 years old especially should be aware of the rare but increased risk of this adverse event. There are other COVID-19 vaccine options available for which this risk has not been seen. Learn more about J&J/Janssen COVID-19 Vaccine and TTS.

- CDC and FDA are monitoring reports of Guillain-Barré Syndrome (GBS) in people who have received the J&J/Janssen COVID-19 Vaccine. GBS is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. Most people fully recover from GBS, but some have permanent nerve damage. After more than 14.9 million J&J/Janssen COVID-19 Vaccine doses administered, there have been around 219 preliminary reports of GBS identified in VAERS as of September 29, 2021. These cases have largely been reported about 2 weeks after vaccination and mostly in men, many 50 years and older. CDC will continue to monitor for and evaluate reports of GBS occurring after COVID-19 vaccination and will share more information as it becomes available.
- **Myocarditis and pericarditis after COVID-19 vaccination are rare.** As of September 29, 2021, VAERS has received 1,590 reports of myocarditis or pericarditis among people ages 30 and younger who received COVID-19 vaccine. Most cases have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna), particularly in male adolescents and young adults. Through follow-up, including medical record reviews, CDC and FDA have confirmed 906 reports of myocarditis or pericarditis. CDC and its partners are investigating these reports to assess whether there is a relationship to COVID-19 vaccination. Learn more about COVID-19 vaccines and myocarditis.
- **Reports of death after COVID-19 vaccination are rare.** More than 396 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through October 4, 2021. During this time, VAERS received 8,390 reports of death (0.0021%) among people who received a COVID-19 vaccine. FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. **Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem.** A review of available clinical information, including death certificates, autopsy, and medical records, has not established a causal link to COVID-19 vaccines. However, recent reports indicate a plausible causal relationship between the J&J/Janssen COVID-19 Vaccine and TTS, a rare and serious adverse event—blood clots with low platelets—which has caused deaths  [1.4 MB, 40 pages].

## Related Pages

- › [Safety of COVID-19 Vaccines](#)
- › [Vaccine Adverse Event Reporting System \(VAERS\): What Reports Mean and How VAERS Works](#)

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